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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Subject: Comments on Draft Guidance on Useful Written Consumer Medication Information; Docket No. 2005D-0169, Federal Register: May 26, 2005 (Volume 70, Number 101)

To Whom It May Concern:

The National Community Pharmacists Association (NCPA) is pleased to submit comments to the FDA on its guidance for useful written information provided to community and chain pharmacy patients/customers with their prescription medications. NCPA represents the nation's community pharmacists, including the owners of nearly 24,000 pharmacies and 60,000 of the pharmacists employed by these pharmacies. Independent pharmacies dispense nearly half of all retail prescriptions.

For over 20 years, community pharmacies have voluntarily acted as a significant source of written medication information provided to consumers with their prescriptions. The community pharmacists represented by NCPA support the provision of such information when given in conjuction with oral instruction from the patient's healthcare professionals—such as the patient's pharmacist or prescriber.

It's important to note that most community and chain pharmacies do not control CMI content. The majority of pharmacies receive CMI from software vendors, who receive CMI content from the presription information database publishers. Therefore,

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prescription information database publishers have ultimate control over what is included in the CMI content.

An overarching void we noticed in the Draft Guidance is that there is no mechanism to measure the content and formatting of medication information as to how it resonates with the average patient and results in improved outcomes. This evidence based data is imperative to construct the most useful and effective CMI. Without this data, putting together CMI criteria is like navigating without a map. We ask that the FDA make provisions to determine this information before issuing its final Guidance.

Regarding the Draft Guidance on Useful Written Consumer Medication Information submitted for comment, there are several concerns. Both the analysis reported by the national expert panel led by Bonnie Svarstad, Ph.D. and the Action Plan for the Provision of Useful Prescription Medicine Information should have laid the foundation for this FDA Draft Guidance. We were disappointed not to see more use of the National Council on Patient Information and Education (NCPIE) recommendations for CMI criteria used in the Draft Guidance as a source for adding clarity where not provided by the Action Plan or the Svarstad study. When comparing the Action Plan and Svarstad study with the Draft Guidance discrepancies exist that conflict with the goals outlined in P.L. 104-180. These include deviations from the Action Plan in content, lack of specificity in recommendation, and the incorporation of extraneous information into the CMI.

Deviations from the Action Plan

It was originally stated that the Draft Guidance was based on the Action Plan for the Provision of Useful Prescription Medicine Information because it provides "specific

recommendations regarding the minimum appropriate characteristics of useful CMI" (Lines 140-142, 162). However, there are several areas in which the FDA's recommendations are not consistent with the original criteria detailed in the Action Plan. According to both the Action Plan and the analysis that was generated by Dr. Svarstad, there was no mention of "monitor for improvement" (Line 172) as is listed in the Draft Guidance. Monitoring for *adverse reactions* is stated in Criterion 5 of the Svarstad analysis but monitoring for adverse reactions differs greatly from "monitoring for improvement." Such lack of clarity can result in a great variance in the length of the CMI, leading to an exorbitant amount of paper consumption and cost assumption for the pharmacy as well as excessive information for the patient. We recommend that the phrase "monitor for improvement" be deleted and replaced with the verbiage stated in Criterion 5.

Additionally, there has been a deviation in the wording used regarding precautions. The Draft Guidance states "that the CMI include all information stated in the PI regarding what precautions the patient should take while using the drug to avoid negative consequences" (Lines 263-264). In contrast, the Action Plan indicates that a statement or statements of precaution "are encouraged in serious situations." All negative consequences are not considered serious situations. For example, if a medicine has a "negative consequence" of a runny nose, does the FDA consider that a "serious condition?" By changing the wording from "serious situations" to "negative consequences," the list of precautions will become impossible to be quantified and so exhaustive that it's usefulness will be diminished. We ask that the Draft Guidance be changed back to the original Action Plan language that statements of precautions "are encouraged in serious situations."

Areas Requiring Greater Specificity

Several grey areas exist in the Draft Guidance. FDA's suggestion for the "appropriate" headings/order to be non-prescriptive (Line 391-404) is an example of the lack of specificity needed to effectively comply with the criteria for useful CMI. Although Appendix G of the Action Plan is acknowledged as a reference in formatting CMI (Line 160), there are no concrete examples given in the Draft Guidance. Again, it is essential for prescription information database publishers to have a concrete format in order for them and ultimately community and chain pharmacies to adhere to the Action Plan's guidelines for usefulness.

Regarding "a validated readability instrument" (Line 349), greater specification of what readability instrument(s) FDA considers validated (e.g. Flesch-Kincaid vs. MSWord) is needed. Without more defined expectations/recommendations, there is a great deal of room for misinterpretation and non-adherence to the Draft Guidance.

Inclusion of Excessive Information

Several recommendations made by the FDA regarding CMI recognized as useful places emphasis on the information being derived from the package insert (Lines 144-147). The FDA has suggested that "all FDA-approved indications listed in the PI" (Line 185) and "all contraindications listed in the PI" (Line 199) be included in the CMI in order to be acknowledged as useful. (We assume FDA is referring to the professional labeling when the term "package insert" is used as opposed to the patient package insert

that is included in the packaging of certain drugs, such as oral contraceptives.) The inclusion of this amount of information begins to shift the content of CMI towards FDA Medguide formatting which is beyond the intent of the recommendation. Additionally, by including such an extensive list, there is an increased likelihood of overwhelming the patient with information. In a study published in The Pharmaceutical Journal Vol. 264 No.7083 p268-270, February 12, 2000, a U.K study found that the length of a patient information leaflet is inversely proportionate to the amount read by the patient. Additionally, this suggested criterion makes no allowance for medications used for non-indicated purposes. For example, when the drug is being used for non-indicated uses (e.g. amitryptiline for neuropathic pain, clonidine for ADHD, etc.) the CMI would not reflect these common off-label uses. Situations like this are common. Ignoring off-label uses and requiring a list of all indicated uses could create confusion resulting in reduced adherence and poor outcomes. We ask FDA to modify its Draft Guidance to state that "common uses and contraindications must be included in the CMI."

Also, the recommendation of including the "5 to 9 most frequently occurring (common) adverse reactions" (Line 298-299) may be impossible for database publishers to meet. Is the range of 5 to 9 evidence based or subjective? What is to be done in cases where a medication has less than 5 or greater than 9 common adverse reactions? We recommend FDA modify its Guidance to read, "the most frequently occurring (common) adverse reactions".

It is to be reiterated that quality written information is essential in providing care to patients only when it is combined with oral information from a licensed pharmacist. Without oral reinforcement from the pharmacist, the CMI becomes another piece of

paper that might or might not be read by the patient and, even if read, may result in unintended negative medication safety or adherence consequences. Any misuse or misinterpretation of CMI threatens patient safety.

In summary, while the FDA Draft Guidance provides helpful information to assist prescription information database publishers, pharmacy software vendors, and pharmacies to comply with the Rule, the Guidance is too vague. Clarity is needed to provide useful and effective guidance. We ask you to incorporate the modifications outlined above. If we may provide additional information or elaborate on these comments, please contact Kenneth L. Riddle, Pharm.D, NCPA Assistant Director, Professional Affairs (703-838-2698).

Sincerely,

/John M Rector

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